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MERCK & CO., INC.

7  
8 UNITED STATES DISTRICT COURT  
9 EASTERN DISTRICT OF CALIFORNIA  
10

11 MARTIN SMITH, JULIE SMITH,

12 Plaintiffs,

13  
14 v.

15 MERCK & CO., INC., and Does 1  
16 Through 25, inclusive

17 Defendants.  
18  
19

CASE NO. 2:07-CV-01608-GEB-KJM

**DEFENDANT MERCK & CO., INC.'S  
ANSWER TO COMPLAINT**

**DEMAND FOR JURY TRIAL**

20  
21 Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned  
22 attorneys, hereby answers those allegations of Plaintiffs' Complaint ("Complaint")  
23 directed to it. To the extent the allegations of any paragraph are directed at defendants  
24 other than Merck, Merck is not required to respond to those allegations. To the extent a  
25 response is deemed necessary, Merck states that it denies all such allegations, except  
26 those that are specifically admitted below. Merck denies all allegations set forth in the  
27 Complaint directed at Merck except to the extent such allegations are specifically  
28 admitted below:

**I. JURISDICTION AND VENUE**

1  
2 1. The allegations of the first sentence of Paragraph 1 are conclusions of law  
3 to which no response is required. To the extent that a response is required, Merck  
4 denies each and every allegation of the first sentence of Paragraph 1. As to the  
5 allegations of the second sentence of Paragraph 1, Merck is without knowledge or  
6 information sufficient to form a belief as to these allegations, except that Merck admits  
7 that it is a corporation organized under the laws of the State of New Jersey with its  
8 principal place of business in New Jersey. As to the allegations in the third sentence of  
9 Paragraph 1, Merck admits for jurisdictional purposes only, that Plaintiffs seek in  
10 excess of \$75,000.

11 2. The allegations of Paragraph 2 are conclusions of law to which no  
12 response is required. To the extent a response is required, Merck denies the allegations  
13 of Paragraph 2.

14 3. The allegations of Paragraph 3 do not require a response.

**II. PARTIES**

15  
16 4. Merck is without knowledge or information sufficient to form a belief as to  
17 the allegations of Paragraph 4.

18 5. Merck denies each and every allegation of Paragraph 5, except admits that  
19 it is a New Jersey corporation with is principal place of business in New Jersey.

20 6. Merck admits that it is registered to do business in the States of California  
21 and New York.

22 7. Merck is without knowledge as to what is meant by the phrase "regularly  
23 transacted," so the allegations in Paragraph 7 are denied.

24 8. Merck denies each and every allegation of Paragraph 8, except that it  
25 admits that Merck manufactured, marketed, and distributed the prescription medicine  
26 FOSAMAX® in accordance with its approved prescribing information. Merck denies  
27 any allegations in Paragraph 8 inconsistent with that prescribing information and  
28 respectfully refers the Court to the Physician's Desk Reference ("PDR") for

1 FOSAMAX® for its actual language and full text.

2 9. Merck admits only that it distributed FOSAMAX® for prescription in  
3 accordance with its approved prescribing information and denies any allegations in  
4 Paragraph 9 inconsistent with that prescribing information. Merck respectfully refers  
5 the Court to the PDR for FOSAMAX® for its actual language and full text. Except as  
6 expressly admitted herein, Merck denies the remaining allegations of Paragraph 9.

7 10. Merck is without knowledge as to what is meant by the phrase “substantial  
8 revenue,” so the allegations in Paragraph 10 are denied.

9 11. Merck is without knowledge as to what is meant by “consequences,” so the  
10 allegations in Paragraph 11 are denied.

### 11 **III. SUMMARY OF THE CASE**

12 12. Merck denies each and every allegation of Paragraph 12, except that it  
13 admits that Merck manufactured, marketed, and distributed the prescription medicine  
14 FOSAMAX® for prescription in accordance with its approved prescribing information.

15 13. Merck denies each and every allegation of Paragraph 13.

16 14. Merck denies each and every allegation of Paragraph 14.

17 15. Merck denies each and every allegation of Paragraph 15.

18 16. Merck denies each and every allegation of Paragraph 16.

### 19 **IV. FACTUAL BACKGROUND**

20 17. Merck denies each and every allegation of Paragraph 17, except that it  
21 admits that Merck manufactured, marketed, and distributed the prescription medicine  
22 FOSAMAX® for prescription in accordance with its approved prescribing information.

23 18. Merck denies each and every allegation of Paragraph 18, except that  
24 Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture  
25 and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription  
26 medication approved by the FDA for prescription in accordance with its approved  
27 prescribing information. Merck denies any allegations in Paragraph 18 inconsistent  
28 with that prescribing information.

1           19. Merck admits only that FOSAMAX® is a prescription medication  
2 approved by the FDA for prescription in accordance with its approved prescribing  
3 information and denies any allegations in Paragraph 19 inconsistent with that  
4 prescribing information. Merck also refers the Court to the prescribing information for  
5 Aredia and Zometa, and denies any allegations in Paragraph 19 with respect to Aredia  
6 and Zometa inconsistent with that prescribing information.

7           20. Merck admits only that some bisphosphonates contain nitrogen and some  
8 do not and that FOSAMAX® is a prescription medication approved by the FDA for  
9 prescription in accordance with its approved prescribing information. Merck denies any  
10 allegations in Paragraph 20 inconsistent with that prescribing information. Merck  
11 respectfully refers the Court to the PDR for FOSAMAX® for its actual language and  
12 full text. Merck also refers the Court to the prescribing information for Aredia,  
13 Bondronat, Didronel, Bonefos, Loron, and Skelid, and denies any allegations in  
14 Paragraph 20 with respect to Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid  
15 inconsistent with that prescribing information. Merck denies the remaining allegations  
16 of Paragraph 20.

17           21. Merck denies each and every allegation of Paragraph 21.

18           22. Merck denies each and every allegation of Paragraph 22.

19           23. Merck denies each and every allegation of Paragraph 23.

20           24. Merck is without knowledge or information sufficient to form a belief as to  
21 the allegations of Paragraph 24.

22           25. Merck denies each and every allegation of Paragraph 25.

23           26. Merck denies each and every allegation of Paragraph 26.

24           27. Merck denies each and every allegation of Paragraph 27.

25           28. Merck denies each and every allegation of Paragraph 28.

26           29. Merck denies each and every allegation of Paragraph 29, except that  
27 Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but  
28 respectfully refers the Court to said document for its actual language and full text.

30. Merck denies each and every allegation of Paragraph 30.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32.

33. Merck denies each and every allegation of Paragraph 33, except that Merck admits that Fosamax product sales in 2005 amounted to approximately \$3.19 billion.

34. Merck is without knowledge as to whether Plaintiff used FOSAMAX®. Merck denies the remaining allegations in Paragraph 34.

35. Merck denies each and every allegation of Paragraph 35.

36. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX®. Merck denies the remaining allegations in Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 38.

39. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 39.

40. Merck denies each and every allegation of Paragraph 40.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

44. Merck denies each and every allegation of Paragraph 44.

45. Merck denies each and every allegation of Paragraph 45.

## COUNTS

### COUNT I: NEGLIGENCE

46. Merck repleads its answers to Paragraphs 1 through and including 45, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

1           47. The allegations in Paragraph 47 are conclusions of law to which no  
2 response is required; to the extent that a response is deemed necessary, the allegations  
3 are denied and Merck respectfully refers the Court to the relevant legal standard,  
4 including any conflict of law rules.

5           48. Merck denies each and every allegation of Paragraph 48, including each  
6 and every allegation contained in subparts (a) through (f).

7           49. Merck denies each and every allegation of Paragraph 49.

8           50. Merck denies each and every allegation of Paragraph 50.

9           51. Merck denies each and every allegation of Paragraph 51.

10                           **COUNT II: STRICT LIABILITY**

11           52. Merck repleads its answers to Paragraphs 1 through and including 51, and  
12 by this reference hereby incorporates the same herein in this paragraph, and makes the  
13 same a part hereof as though fully set forth *verbatim*.

14           53. Merck denies each and every allegation of Paragraph 53, except that it  
15 admits that Merck manufactured, marketed and distributed the prescription medicine  
16 FOSAMAX® for prescription in accordance with its approved prescribing information  
17 and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff  
18 alleges she consumed.

19           54. Merck denies each and every allegation of Paragraph 54, except that it  
20 admits that Merck manufactured, marketed and distributed the prescription medicine  
21 FOSAMAX® for prescription in accordance with its approved prescribing information  
22 and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff  
23 alleges she consumed.

24           55. Merck is without knowledge or information sufficient to form a belief as to  
25 the allegations of Paragraph 55.

26           56. Merck denies each and every allegation of Paragraph 56.

27           57. Merck denies each and every allegation of Paragraph 57.

28           58. Merck denies each and every allegation of Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59.

60. Merck denies each and every allegation of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63.

64. Merck denies each and every allegation of Paragraph 64.

**COUNT III: BREACH OF EXPRESS WARRANTY**

65. Merck repleads its answers to Paragraphs 1 through and including 64, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

66. Merck denies each and every allegation of Paragraph 66, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

67. Merck denies each and every allegation of Paragraph 67.

68. Merck denies each and every allegation of Paragraph 68.

69. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 69.

70. Merck denies each and every allegation of Paragraph 70.

71. Merck denies each and every allegation of Paragraph 71.

72. Merck denies each and every allegation of Paragraph 72.

**COUNT IV: BREACH OF IMPLIED WARRANTY**

73. Merck repleads its answers to Paragraphs 1 through and including 72, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

74. Merck denies each and every allegation of Paragraph 74, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine

FOSAMAX® for prescription in accordance with its approved prescribing information.

75. Merck denies each and every allegation of Paragraph 75, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

76. Merck denies each and every allegation of Paragraph 76.

77. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 77.

78. Merck denies each and every allegation of Paragraph 78.

79. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 79.

80. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 80.

81. Merck denies each and every allegation of Paragraph 81.

82. Merck denies each and every allegation of Paragraph 82.

83. Merck denies each and every allegation of Paragraph 83.

**COUNT V: FRAUDULENT MISREPRESENTATION**

84. Merck repleads its answers to Paragraphs 1 through and including 83, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

85. Merck denies each and every allegation of Paragraph 85, including each and every allegation contained in subparts (a) through (b).

86. Merck denies each and every allegation of Paragraph 86.

87. Merck denies each and every allegation of Paragraph 87.

88. Merck denies each and every allegation of Paragraph 88.

89. Merck denies each and every allegation of Paragraph 89.

90. Merck denies each and every allegation of Paragraph 90.

91. Merck denies each and every allegation of Paragraph 91.

92. Merck denies each and every allegation of Paragraph 92.

93. Merck denies each and every allegation of Paragraph 93.

**COUNT VI: FRAUDULENT CONCEALMENT**

94. Merck repleads its answers to Paragraphs 1 through and including 93, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

95. Merck denies each and every allegation of Paragraph 95, including each and every allegation contained in subparts (a) through (b).

96. Merck denies each and every allegation of Paragraph 96.

97. Merck denies each and every allegation of Paragraph 97.

98. Merck denies each and every allegation of Paragraph 98.

99. Merck denies each and every allegation of Paragraph 99.

100. Merck denies each and every allegation of Paragraph 100.

101. Merck denies each and every allegation of Paragraph 101.

102. Merck denies each and every allegation of Paragraph 102.

**GLOBAL PRAYER FOR RELIEF**

Merck denies that Plaintiffs are entitled to any of the relief requested in their Global Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**AFFIRMATIVE DEFENSES**

Discovery and investigation may reveal that any one or more of the following additional defenses should be available to Merck in this matter. Merck, therefore, asserts said additional defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these additional defenses as it may deem appropriate. Further, Merck reserves the right to

1 amend its Answer to assert additional defenses, cross-claims, counterclaims, and other  
2 claims and defenses as discovery proceeds. Further answering and by way of additional  
3 defense, Merck states as follows:

4 **FIRST AFFIRMATIVE DEFENSE**

5 Each and every claim asserted or raised in the Complaint is barred by the  
6 applicable statute of limitations and is otherwise untimely.

7 **SECOND AFFIRMATIVE DEFENSE**

8 The Complaint fails to state a claim upon which relief can be granted.

9 **THIRD AFFIRMATIVE DEFENSE**

10 Each and every claim asserted or raised in the Complaint is barred by the  
11 doctrines of estoppel, waiver or statutory and regulatory compliance.

12 **FOURTH AFFIRMATIVE DEFENSE**

13 If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon  
14 information and belief, such injuries or losses were caused in whole or in part through  
15 the operation of nature or other intervening cause or causes.

16 **FIFTH AFFIRMATIVE DEFENSE**

17 To the extent that Plaintiffs assert claims based on Merck's adherence to and  
18 compliance with applicable state laws, regulations and rules, such claims are preempted  
19 by federal law under the Supremacy Clause of the United States Constitution.

20 **SIXTH AFFIRMATIVE DEFENSE**

21 To the extent that Plaintiffs assert claims based upon an alleged failure by Merck  
22 to warn Plaintiffs directly of alleged dangers associated with the use of FOSAMAX®,  
23 such claims are barred under the learned intermediary doctrine because Merck has  
24 discharged its duty to warn in its warnings to the prescribing physician.

25 **SEVENTH AFFIRMATIVE DEFENSE**

26 Other persons or entities who are not parties to this suit were guilty of negligence  
27 which was the sole proximate cause of, or a contributing cause to, the damages alleged  
28 in the Complaint. Merck anticipates more specific information regarding the identity

1 and potential liability of these non-parties will be developed during discovery.

2 Accordingly, any damages awarded should be apportioned.

3 **EIGHTH AFFIRMATIVE DEFENSE**

4 The injuries and damages, if any, sustained by the Plaintiffs resulted in whole or  
5 in part from their own comparative negligence and any damages recovered should be  
6 reduced accordingly.

7 **NINTH AFFIRMATIVE DEFENSE**

8 If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such  
9 injuries or losses were only sustained after Plaintiffs knowingly, voluntarily, and  
10 willfully assumed the risk of any injury as the result of the consumption of,  
11 administration of, or exposure to any medicine or pharmaceutical preparation  
12 manufactured or distributed by Merck or another manufacturer.

13 **TENTH AFFIRMATIVE DEFENSE**

14 If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon  
15 information and belief, such injuries and losses were caused by the actions of persons  
16 not having real or apparent authority to take said actions on behalf of Merck and over  
17 whom Merck had no control and for whom Merck may not be held accountable.

18 **ELEVENTH AFFIRMATIVE DEFENSE**

19 If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon  
20 information and belief, such injuries and losses were proximately caused by Plaintiffs'  
21 misuse or abuse of FOSAMAX®.

22 **TWELFTH AFFIRMATIVE DEFENSE**

23 If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such  
24 injuries or losses resulted from Plaintiffs' pre-existing and/or unrelated medical, genetic  
25 and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions,  
26 subsequent medical conditions or natural courses of conditions for which this  
27 Defendant is not responsible.

**THIRTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims for breach of warranty are also barred for lack of timely notice of breach and/or lack of privity.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**SIXTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiffs seek punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**TWENTIETH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other

1 medicine or pharmaceutical preparation Plaintiff alleges to have taken within the  
2 meaning of comment j to Section 402A of the Restatement (Second) of Torts.

3 **TWENTY-FIRST AFFIRMATIVE DEFENSE**

4 Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third)  
5 of Torts: Products Liability.

6 **TWENTY-SECOND AFFIRMATIVE DEFENSE**

7 Plaintiffs' claims are barred under comment f to Section 6 of the Restatement  
8 (Third) of Torts: Products Liability.

9 **TWENTY-THIRD AFFIRMATIVE DEFENSE**

10 There is no practical or technically feasible alternative design that would have  
11 reduced the alleged risk without substantially impairing the reasonably anticipated and  
12 intended function of FOSAMAX®.

13 **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

14 Plaintiffs' claims are barred in whole or in part by failure to mitigate damages.

15 **TWENTY-FIFTH AFFIRMATIVE DEFENSE**

16 Plaintiffs' claims are barred in whole or in part because Merck's conduct  
17 conforms with medical knowledge.

18 **TWENTY-SIXTH AFFIRMATIVE DEFENSE**

19 With respect to each and every cause of action, Plaintiffs are not entitled to  
20 recovery for strict liability because Plaintiffs cannot state claims founded in strict  
21 liability because, among other things, comments j and k to Section 402A of the  
22 Restatement (Second) of Torts relegates Plaintiffs' claims to a negligence cause of  
23 action.

24 **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

25 All activities of Merck as alleged in the Complaint were expressly authorized  
26 and/or regulated by a government agency. Therefore, Plaintiffs' claims pertaining to  
27 unfair or deceptive practices are barred.  
28

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiffs are not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the Constitution of the United States and the Constitution of California.

**THIRTIETH AFFIRMATIVE DEFENSE**

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

At all times relevant herein, any product which is the subject matter of this action processed and distributed by Merck in any state in the United States was processed and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

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310-229-9900

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs have not sustained an ascertainable loss of property or money.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs have not suffered any actual injury or damages.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred under the doctrine of economic loss.

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

**THIRTY-NINTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

**FORTIETH AFFIRMATIVE DEFENSE**

Plaintiffs' claims of fraud are not pleaded with the required particularity.

**FORTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs cannot recover for the claims asserted because Plaintiffs have failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiffs.

**FORTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims for breach of warranty are barred because Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of

1 privity and/or because the alleged warranties were disclaimed.

2 **FORTY-THIRD AFFIRMATIVE DEFENSE**

3 An asymptomatic plaintiff lacks standing because she has suffered no damages  
4 and no injury-in-fact.

5 **FORTY-FOURTH AFFIRMATIVE DEFENSE**

6 To the extent that Plaintiffs assert claims based on Merck's adherence to and  
7 compliance with applicable state laws, regulations and rules, such claims are preempted  
8 by federal law under the Final Rule, Requirements on Content and Format of Labeling  
9 for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269  
10 (January 24, 2006).


11 **PRAYER FOR RELIEF**

12 WHEREFORE, Merck prays as follows:

- 13 1. That Plaintiffs take nothing by the Complaint;  
14 2. That this action be dismissed with prejudice;  
15 3. That Merck be awarded its costs of suit herein, and its attorney's fees to  
16 the extent provided for by statute or contract;  
17 4. For such other and further relief as the Court deems just and proper.

18  
19 Dated: August 30, 2007

20 VENABLE LLP  
21 DOUGLAS C. EMHOFF  
22 JEFFREY M. TANZER

23  
24 By   
25 Jeffrey M. Tanzer  
26 Attorneys for Defendant  
27 Merck & Co., Inc.  
28

**DEMAND FOR JURY TRIAL**

Merck demands a trial by jury as to all issues so triable.

Dated: August 30, 2007

VENABLE LLP  
DOUGLAS C. EMHOFF  
JEFFREY M. TANZER

By



Jeffrey M. Tanzer  
Attorneys for Defendant  
Merck & Co., Inc.

VENABLE LLP

2049 CENTURY PARK EAST, SUITE 2100  
LOS ANGELES, CA 90067  
310-229-9900

**PROOF OF SERVICE**

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is Venable LLP, 2049 Century Park East, Suite 2100, Los Angeles, California.

On August 30, 2007, I served the foregoing document(s) described as **DEFENDANT MERCK & CO., INC.'S ANSWER TO COMPLAINT; DEMAND FOR JURY TRIAL** on the interested parties in this action addressed as follows:

Attorneys for Plaintiffs

Clayeo C. Arnold  
Clifford L. Carter  
Kirk J. Wolden  
CLAYEO C. ARNOLD, P.C.  
608 University Avenue  
Sacramento, CA 95825

☒ By placing true copies thereof enclosed in a sealed envelope(s) addressed as stated above.

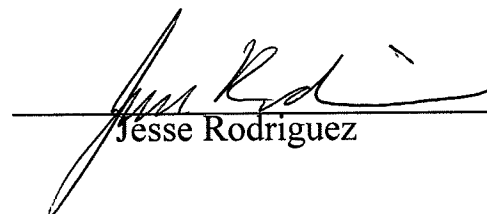
☒ **BY MAIL (CCP §1013(a)&(b)):** I am readily familiar with the firm's practice of collection and processing correspondence for mailing with the U.S. Postal Service. Under that practice such envelope(s) is deposited with the U.S. postal service on the same day this declaration was executed, with postage thereon fully prepaid at 2049 Century Park East, Suite 2100, Los Angeles, California, in the ordinary course of business.

☐ **BY OVERNIGHT DELIVERY (CCP §1013(c)&(d)):** I am readily familiar with the firm's practice of collection and processing items for delivery with Overnight Delivery. Under that practice such envelope(s) is deposited at a facility regularly maintained by Overnight Delivery or delivered to an authorized courier or driver authorized by Overnight Delivery to receive such envelope(s), on the same day this declaration was executed, with delivery fees fully provided for at 2049 Century Park East, Suite 2100, Los Angeles, California, in the ordinary course of business.

Executed on August 30, 2007 at Los Angeles, California

☐ **(STATE)** I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

☒ **(FEDERAL)** I declare that I am employed in the office of a member of the Bar of this Court at whose direction the service was made. I declare under penalty of perjury under the laws of the United States of America that the above is true and correct.

  
Jesse Rodriguez